

REMARKS

This is in response to the Office Action mailed July 18, 2007, in which the Examiner rejected claims 243-274. With this Amendment, Applicant has amended claims 243, 246-249, 251-254, 257-260, 264, 266-269, 271 and 273. Reconsideration of the application, as amended, is respectfully requested.

Amendments

Independent claims 243, 249, 254, 260, 269 and 273 have been amended to include “implanting a stimulator device in the patient” and “driving the at least one electrode . . . using the stimulator device”. Support for the amendments can be found in paragraph [0139] of the application. Additionally, claims 246, 251, 257 and 266 have each been amended to describe the method of the corresponding independent claim as “further comprising contracting the pelvic muscle in response to driving the at least one electrode, wherein urine flow through a urethra of the patient is inhibited.” Support for the amendments can be found in paragraph [0173] of the application. Claims 264 and 271 have been amended to recite “wherein driving the at least one electrode comprises providing for the waveform a plurality of pulses each having a duration of less than 1 ms”. Support for the amendment can be found in paragraph [0179] of the application. No new matter has been added.

Non-statutory Double Patenting

In Sections 2-4 of the Office Action, the Examiner rejected claims 243-274 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 10-13, 17-20 and 22-25 of U.S. Patent No. 6,896,651, over claims 17-18, 21, 23-24, 46-51 and 53 of U.S. Patent No. 6,652,449, and over claims 40, 44, 46-50, 52, 61-62 and 69 of U.S. Patent No. 6,354,991. While not necessarily agreeing with these rejections, Applicant is filing a terminal disclaimer against these three patents in order to expedite allowance of the present application.

Claim Rejections – 35 U.S.C. §103

In Section 6 of the Office Action, the Examiner rejected claims 243-274 under 35 U.S.C. §103(a) as being unpatentable over Suda et al. (U.S. Patent No. 5,978,712). Applicant respectfully believes that the rejections can be withdrawn for the reasons set forth below.

Overview

Suda et al. is directed to “a stimulating apparatus for preventing urinary incontinence which applies electrical or magnetic stimulation to a patient suffering from urinary incontinence, and which records the progress of stimulation.” Col. 1, lines 7-10. Suda et al. also describe a stimulation treatment in the Background section that “is continued for one week to several months” (Col. 1, lines 23-24). Col. 1, lines 28-34 provides:

In the treatment with electrical stimulation, specifically, the patient goes to the hospital once each week for several months to be treated with stimulation for 15 to 30 minutes, or, in accordance with instructions of the doctor, the patient is subjected at home two or three times a day to stimulation for about 20 minutes by using a portable electric stimulating apparatus.

Suda et al. further do not describe their stimulating apparatus 15 as one that is implanted in the patient. Rather, the apparatus 15 “may be housed in a small case, and then carried while being fixed to the waist of the patient with a belt [or] the apparatus may be put into a pocket of clothes of the patient.” Col. 5, lines 8-12. This is likely due to the relatively temporary use of the stimulating apparatus of Suda et al. in their incontinence treatment method.

Unlike Suda et al., embodiments of the present invention utilize a stimulator device (20) that is implanted in the patient and operates to selectively inhibit undesired urine flow through the application of an electrical waveform to a pelvic muscle (paragraphs [0139], [0173]). The implantation of the stimulator device in the patient represents a long term solution to urinary incontinence for the patient rather than the temporary treatment described in Suda et al.

Claim Rejections

As provided in MPEP 2143, one of the three basic criteria that must be met in order to form a *prima facie* case of obviousness against a claim is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” (Applicant’s emphasis)

Independent claims 243, 249, 254, 260, 269 and 273 are non-obvious in view of Suda et al. because the reference fails to disclose all of the claimed elements. For instance, Suda et al. fail to disclose “implanting a stimulator device in the patient” or “driving the at least one electrode . . . using the stimulator device”, as provided in each of the independent claims. Rather, Suda et al. only disclose a stimulator device that is located externally to the patient, as described above. Therefore, each of the independent claims is non-obvious in view of Suda et al. because the reference fails to disclose all of the claimed elements.

Additionally, each of the claims depending from the independent claims are non-obvious in view of Suda et al. for at least the reasons set forth above. Therefore, Applicant requests that the rejections be withdrawn.

Additional grounds for withdrawing the rejections of some of the claims, are provided below.

With regard to independent claims 249, Suda et al. do not disclose “driving the at least one electrode to apply a biphasic electrical waveform to the muscle using the stimulator device.” Should the Examiner disagree with this finding, Applicant requests that the Examiner specifically identify the subject matter of Suda et al. that “reads on” the claimed language.

With regard to independent claim 273, Suda et al. do not disclose “implanting at least one elongated electrode structure in general alignment with a urethra of a patient, in contact with the pelvic muscle of the patient”, as provided in the claim. Should the Examiner disagree with this finding, Applicant requests that the Examiner specifically identify the subject matter of Suda et al. that “reads on” the claimed language.

Claims 244, 265 and 272 each provide “wherein providing the range of pulse width durations comprises setting the range of pulse width durations to be selectable from 0.1 ms to 2

ms.” The Examiner found Suda et al. to disclose “the claimed methods except for specifically teaching a pulse width duration between 0.1 ms and 2 ms . . .” Even so, the Examiner found the subject matter to be obvious in view of Suda et al. due to the teaching “that many perimeters may be varied depending on the individual and particular cases.” Based on this finding, the Examiner concluded that

“a modification of Suda et al. such that the electrical stimulation is delivered to the pelvic muscle to treat incontinence at the particular pulse width duration would have been obvious to one skilled in the art since it is considered to be a matter of routine engineering design choice to discover the optimum or workable ranges and the particular ranges must produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.” Applicant respectfully disagrees with these findings.

Applicant respectfully believes that this finding is improper.

MPEP 2144.05 addresses the obviousness of ranges. However, MPEP 2144.05 does not eliminate the requirement that a prior art reference must “teach or suggest all claim limitations” as provided in MPEP 2143, as the Examiner appears to contend. Rather, MPEP 2144.05 merely explains circumstances where a claimed range is obvious in view of a range disclosed by the prior art even though the range disclosed by the prior art is not identical to the claimed range. For example, MPEP 2144.05 provides “In the case where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’ a *prima facie* case of obviousness exists” (quoting In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)) and “[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness” (quoting In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)) .

In making the rejections, the Examiner did not identify any disclosure by Suda et al. of a range of pulse width durations that either identically discloses the range provided in claims 244, 265 and 272, or otherwise renders the claimed range obvious based on any one of the grounds provided MPEP 2144.05. Therefore, claims 244, 265 and 272 are non-obvious in view of Suda et al.

With regard to claims 264 and 271, Suda et al. do not disclose “wherein driving the at least one electrode comprises providing for the waveform a plurality of pulses each having a duration of less and 1 ms”, as provided in the claims. Should the Examiner disagree with this finding, Applicant requests that the Examiner specifically identify the subject matter of Suda et al. that either 1) identically discloses the claimed range or 2) provides a range that renders the claimed range obvious based on one of the circumstances described in MPEP 2144.05.


Conclusion

Applicant respectfully believes that the application, as amended, is in condition for allowance. Entry of the amendments and allowance of the application is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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